CLINICAL CENTER

PATIENT SAFETY PLAN

2003-2004

TABLE OF CONTENTS

I. Goals of the Clinical Center Patient Safety Program

II. Organizational Structures and Functions Supporting Patient Safety

III. Patients as Partners in Safety

IV. Patient Safety Staff Education
    a. Patient Safety Orientation
    b. Ongoing Patient Safety Training
    c. National Patient Safety Goals
    d. Occurrence Reporting System
    e. Performance Improvement
    f. Team Training

V. Safety Improvement Activities
    a. Patient Safety Nomenclature
    b. Patient Safety Performance Data Sources
        1) Occurrence Reporting System
        2) Safety Rounds
        3) Leadership Rounds
        4) Risk Assessments
        5) Medication Errors/Pharmacy Interventions
        6) Nosocomial Infection Surveillance
        7) Staff Perceptions
        8) Patient Perceptions
        9) Patient Representative
        10) Patient Advisory Group

VI. Sentinel Event Management and the Use of Root Cause Analysis for "Near Misses"

VII. Strategies for Continually Assessing and Reducing Risk
    a. Process for identifying high risk processes
    b. Employee and patient risk assessments
    c. Failure mode and effects analysis

VIII. Patient Safety Research Initiatives

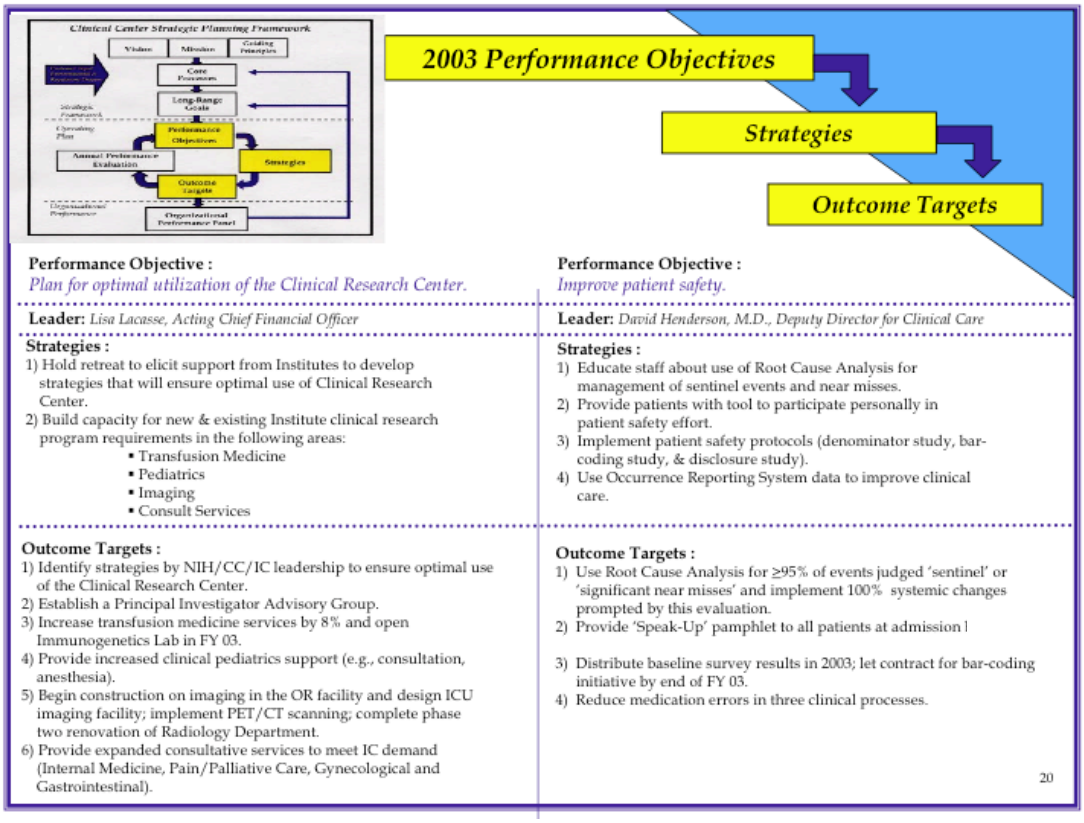
IX. Clinical Center Contributions to Federal and National Patient Safety Initiatives

I. CLINICAL CENTER PATIENT SAFETY PROGRAM GOALS

The long-range goals of the Clinical Center patient safety program are to:

1. Establish an organizational culture and structure that supports:
    - the delivery of safe, transparent, and high quality care to clinical research volunteers;
    - a non-punitive environment that encourages the reporting of, and discussion about, patient care occurrences;
2. Continually seek strategies to improve the timely and efficient reporting of patient care occurrences;
3. Establish effective performance improvement processes that facilitate the management of patient safety issues;
4. Strive to inculcate into every Clinical Center employee's practice their responsibility in the safe delivery of care and services;
5. Develop organization-wide processes that facilitate effective communication about improvement activities and best practices regarding patient safety to all levels of staff.

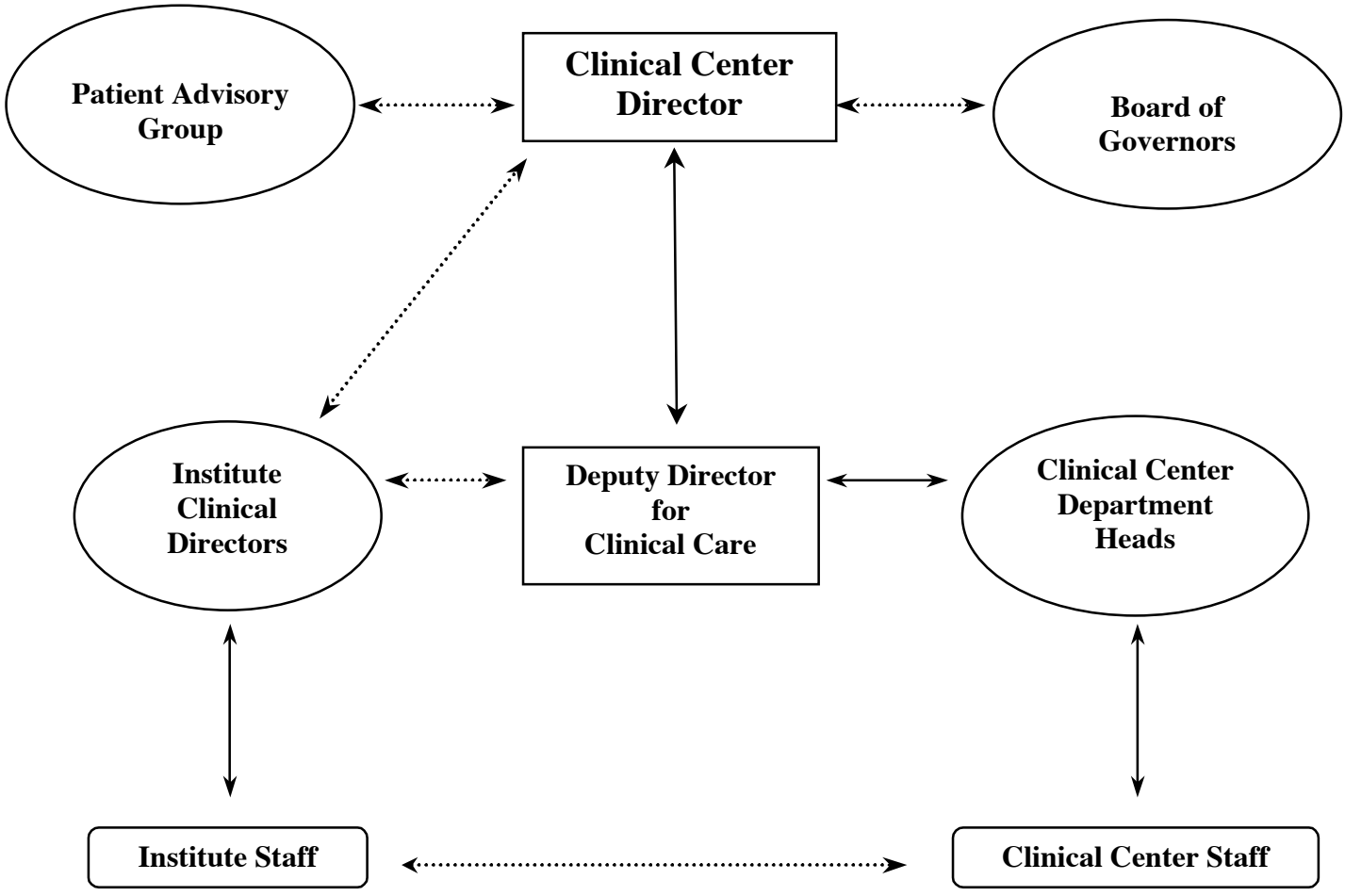
Executive leadership's commitment to patient safety is reflected in the inclusion of specific patient safety goals and outcome targets in the Clinical Center's Strategic and Operating Plan.



II. Organizational Structures and Functions Supporting Patient Safety

The Clinical Center patient safety functions are embedded into the existing committee and performance improvement structure of the Clinical Center. The integration of critical patient safety functions (e.g., education, occurrence reporting, performance measurement) into the existing infrastructure assures that patient safety does not become a stand-alone activity; rather it is part of all Clinical Center patient care and clinical research support activities. The management of patient safety activities and outcomes in the Clinical Center is a shared responsibility among the Clinical Center leadership, Institute leadership, Clinical Center departments, and patient care/support staff. Oversight of patient care quality and patient safety rests with the Director of the Clinical Center. Day to day direction, management, and oversight is managed by the Office of the Deputy Director for Clinical Care, in collaboration with Clinical Center and Institute leadership.

A. Roles Supporting Patient Safety



B. Clinical Center Committee Structure Supporting Patient Safety

Medical Executive Committee
The Medical Executive Committee (MEC) is charged with developing policies and procedures concerning medical care and patient safety in the CC, continually assesses the quality of care in the Clinical Center, and advising the Clinical Center Director regarding allocation of resources for clinical care and patient safety. The MEC makes recommendations to the Director, Clinical Center on all matters related to Medical Staff appointments, clinical privileges, and corrective actions.

Membership consists of the Clinical Directors of the Institutes, the Clinical Center Director, the Deputy Director for Clinical Care, the Associate Director for Patient Care Service, Chief of National Cancer Institute Surgery Branch, Chief of Critical Care Medicine, and the Clinical Center pediatrician.

Clinical Quality Committee
The Clinical Quality Committee (CQC) provides oversight of the Clinical Center's clinical quality improvement program. The CQC provides direction to, and serves as a liaison among, the MEC, the Clinical Center clinical and service departments, the Institutes, and the Clinical Center's administrative staff in matters pertaining to the quality and appropriateness of patient care and patient safety.

Membership includes a broad range of disciplines, representing all Clinical Center Departments and representative institute staff.

Credentials Committee
The Credentials Committee reviews, investigates, and recommends for approval the credentials of all practitioners seeking Medical Staff appointments in the Clinical Center. The Credentials Committee also reviews each department's credentialing and privileging process to assure that all practitioners in the Clinical Center undergo a rigorous and meaningful professional vetting process prior to providing care to Clinical Center patients.

Membership of the Credentials Committee consists of two Institute Clinical Directors, a Clinical Center physician, a surgeon, a dentist, and a member of the Adjunct Staff.

Hospital Infections Committee
The Hospital Infections Committee recommends policies and procedures for the prevention, surveillance, and control of nosocomial infections, and monitors the use of antibiotics.

Membership includes members of the Hospital Epidemiology Service, a broad range of medical and surgical specialties in the Clinical Center, the NIH Occupational Medicine Service, laboratory medicine, nutrition, transfusion medicine, materials management, pharmacy, and nursing.

Pediatric Care Committee
The Pediatric Care Committee advises the MEC and the Clinical Center Director on issues related to the safe care of pediatric patients in the Clinical Center and serves to improve the coordination of pediatric care among the Institutes and Clinical Center departments. The Medication Occurrence Review and Evaluation subcommittee retrospectively reviews aggregate pediatric medication-related data for trends related to pediatric medication use. Recommendations for improvement in pediatric medication processes are forwarded to the Pediatric Care Committee for organizational management.

Membership includes: Clinical Directors (or their designees) representing Institutes with pediatric research focus, nursing, critical care medicine, diagnostic radiology, nutrition, pharmacy, rehabilitation medicine, social work, and spiritual ministry. The Committee is chaired by the Clinical Center pediatrician.

Pharmacy and Therapeutics Committee (P&T Committee)
The P&T Committee is responsible for developing and monitoring policies and procedures pertaining to the safe and appropriate use of drugs and other pharmaceuticals, maintaining the Clinical Center's drug formulary, reviewing adverse drug reactions and other adverse drug events, establishing standards for the management of investigational drugs and oversight of the education of healthcare practitioners about drugs and other pharmaceuticals.

Membership consists of Institute physicians and dentists knowledgeable about drug, biologics, and other pharmaceutical therapies, nursing staff, the Chief of the Pharmacy Department, a clinical pharmacologist, and the Office of the Deputy Director for Clinical Care.

Safety Committee (Environment of Care)
The Safety Committee is responsible for monitoring hospital-wide environmental surveillance activities. Activities of the Safety Committee include: reviewing hazardous surveillance data, conducting surveillance for hazardous environmental situations, establishing Clinical Center-wide policies and procedures to reduce occupational risks, conducting environment of care safety surveys, and developing and maintaining the Clinical Center environmental safety plans.

Members of the Safety Committee include a broad range of Clinical Center and Institute staff, including, but not limited to: nursing, pharmacy, respiratory therapy, nutrition, laboratory medicine, facilities management, biomedical engineering, fire prevention, maintenance, and occupational medicine. The Clinical Center Safety Officer chairs the Committee.

Surgical Administrative Committee (SAC)
The SAC is responsible for the coordination of procedures and policies regarding the provision of surgical services in the Clinical Center and for advising the Medical Executive Committee, the Chief of the Department of Anesthesia and Surgical Services (DASS) and the Clinical Center Director about policy and practice issues related to surgical care.

Membership includes: surgeons from each Institute with a surgical research enterprise, Chief of the DASS, Chief of the Cardiac Catheterization Laboratory, and Clinical Center clinical and administrative staff from the Office of the Deputy Director for Clinical Care.

Transfusion Committee
The Transfusion Committee advises the MEC regarding the safe management and delivery of blood and blood products in the Clinical Center, assures the safety and adequacy of blood and blood products, reviews summaries of all transfusions, reviews transfusion reactions, makes recommendations for improvement in blood administration practices, and reviews and assesses priorities for the appropriate use of blood and blood products.

Membership of the Transfusion Committee consists of staff from transfusion medicine, laboratory medicine, nursing, anesthesia, hematology (NHLBI), pediatric oncology branch, surgery branch, outpatient services, and other representatives, as appropriate.

Standardization Committee
The Standardization Committee is charged with reviewing all new product requests for patient safety and clinical care issues, reviewing all patient-related product recalls, and reviewing and collaboratively investigating occurrence reports involving supplies, products, equipment, and services. The Committee also coordinates staff education related to new product use.

Membership includes a broad range of patient care and administrative staff from Clinical Center departments.

Clinical Center Department Quality Improvement Programs
Each Clinical Center department has a quality improvement program designed to monitor the quality of the patient care and services provided to Clinical Center patients. A key focus of each of these programs is assuring patient safety. Each department's performance measurement panel includes indicators that assess patient safety.

Institute Quality Improvement Programs
Institute staff are responsible for continually assessing and monitoring the quality of clinical research and patient care provided by Institute practitioners. Clinical Directors and Branch Chiefs convene quality improvement conferences to review ongoing care and safety issues. Many programs use the Clinical Center Occurrence Reporting System data to direct improvement activities.

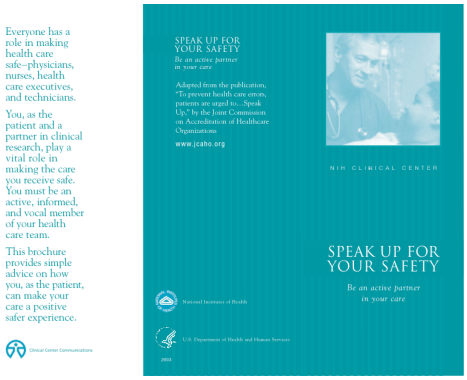
Patient Advisory Group (PAG)
The Patient Advisory Group advises the Director of the Clinical Center regarding issues that directly impact the quality of care and services provided to Clinical Center patients. The PAG serves as the patients' voice for patient safety issues in the Clinical Center. This group provides advice about program design from the patient's perspective and assists in the development of patient education materials and the content of the patient perception surveys. Membership consists of patient volunteers from a variety of Institute clinical research programs.

III. PATIENTS AS PARTNERS IN SAFETY

The primary mission of the Clinical Center is to support the conduct of clinical research. The success of the clinical research enterprise at the Clinical Center is dependent on the development of novel clinical research questions and protocols, the presence of safe clinical care processes to support the conduct of the protocols, and the participation of well informed patient volunteers. Patients that come to the Clinical Center to volunteer to participate in a clinical research protocol are true partners in the clinical research process. Because clinical research involves a certain degree of inherent risk, it is essential that our patient volunteers are fully informed about the clinical research studies in which they are enrolled. The safety of patients participating in a clinical research protocol is a shared responsibility between the Clinical Center practitioners and staff and the patient-volunteers.

The informed consent process is the centerpiece of the patient education process regarding the research process. The Clinical Center has a longstanding commitment to continually assessing and improving the processes with which we inform patients about what to expect as a participant in a research study, as well as about what is expected of them as partners in the process. Each informed consent document is developed using a very prescribed set of requirements and is reviewed by the Institutional Review Board to assure that each document is comprehensive and comprehensible.

Understanding how patients view their experience as a clinical research volunteer at the Clinical Center is a priority of Clinical Center leadership. To facilitate this understanding, a section of the patient perception survey is devoted to querying patients about their perception of the clinical research experience. Several questions specifically address patients' perceptions of the informed consent process. In 2003, data from these surveys led to the establishment of an organizational process redesign effort to improve the quality of the consent process. A series of patient safety related questions also were included on the patient survey (see SectionV,B,8 for more information).



Because healthcare environments are intrinsically risky, the Clinical Center is committed to raising the awareness of our patients about those risks. In collaboration with the Patient Advisory Group, and with input from a broad range of Clinical Center and Institute staff, the Clinical Center developed a patient safety educational brochure for patient use, "SPEAK UP FOR YOUR SAFETY".

IV. Staff Patient Safety Education

Patient safety is freedom from injury or illness resulting from the processes of healthcare.

A. Patient Safety Orientation Training

Each new employee working in the Clinical Center is introduced to the principles of patient safety and the Clinical Center's approach to assuring high quality and safe patient care during new employee orientation.

B. Ongoing Patient Safety Education

The initial patient safety orientation is augmented at the department and/or Institute level by program-specific patient safety training and competency education. Examples of department specific patient safety training include:

Patient Care Services Department

The Patient Care Services Department has a robust patient safety training program that includes detailed training about the use of the Occurrence Reporting System, the use of performance improvement techniques in managing patient safety issues, and extensive training about the value of, and the Clinical Center's response to, the National Patient Safety Goals. The Patient Care Services Department also continually assesses the extramural community for best practices relative to the patient safety and disseminates this information to staff.

Pharmacy Department

The Clinical Center Pharmacy Department provides a detailed educational offering about the Pharmacy Medication Safety Program. Program elements include: medication safety strategies used by the Pharmacy, use of the occurrence reporting system program, definitions and terms for medication-related event reporting, and the Pharmacy's responsibility in assuring organizational compliance with the National Patient Safety Goals. The Pharmacy also supports an educational program on performance improvement and data management. To assure that each staff person has access to this educational information, the Pharmacy includes the following videocasts in their video library or on their website: *Beyond Blame* (Institute for Healthcare Improvement), *Pharmacy Key Processes and Performance Improvement,* and *Using Data to Improve Performance.*

C. National Patient Safety Goals Education

The Office of the Deputy Director for Clinical Care, in collaboration with the Nursing Department, provides ongoing education to key organizational committees (e.g., MEC, CQC, P&T, departmental quality committees), Clinical Center Departments, and Institute staff regarding the organization's response to the JCAHO National Patient Safety Goals.

D. Occurrence Reporting System Training

The Clinical Center Occurrence Reporting System (ORS) is the Clinical Center's primary tool for monitoring clinical care events (see Section V, B, 1 for a description of the ORS). Prior to receiving a password to access the ORS, Clinical Center and Institute staff members complete a training module that includes information about the value to the organization of reporting occurrences, the Clinical Center's approach to managing the data collected in the system, and

the importance of establishing and maintaining a non-punitive culture that encourages reporting of, and open dialogue about, patient care occurrences and medical errors.

E. Performance Improvement Training

Critical to the success of a comprehensive patient safety program is providing staff with the tools necessary to effectively manage data and lead improvement efforts in complex environments. Clinical Center leadership has identified the effective use of performance improvement strategies as a Clinical Center organizational competency. To support this commitment, the Clinical Center provides ongoing training opportunities for staff regarding the principles of quality/performance improvement and performance measurement. Issues discussed as part of Performance Improvement training includes: a) systems thinking; b) team work; c) customer focus; d) service orientation; and e) data driven decision-making.

F. Team Training

Essential to a successful performance improvement program is the deployment of highly functioning teams. Team training is offered to all Clinical Center and Institute employees as part of the Clinical Center's Customer Service Initiative. The curriculum from the Team Training session includes the following modules: the importance of effective communication and use of language; the principles of team interactions; the identification and management of team behaviors; and development of strategies for managing highly effective teams.

V. Patient Safety Improvement Activities

A. Patient Safety Nomenclature

To facilitate the discussion about, and management of, patient safety issues, an extensive "dictionary" of patient safety terms has been vetted for use in the Clinical Center.

B. Sources Patient Safety Performance Data

1) *Occurrence Reporting System*
   The Clinical Center Occurrence Reporting System is the centerpiece of the Clinical Center's performance improvement data collection/event reporting program. Staff have password-protected access to the ORS and are encouraged to voluntarily report care- and service-related events into the web-based database linked to the hospital's Medical Information System (MIS). When a report is entered into the system, an automatic email notification is sent to an organizationally identified "content expert" who is responsible for continued data collection, analysis of trending, and initiating an immediate response in the event of a serious/sentinel event. Patient care unit and departmental managers are responsible for coordinating collaborative follow-up to events reported in the ORS.

Data from the ORS are disseminated on a monthly basis to departments and institutes for use in guiding local performance improvement activities. ORS data are discussed, as appropriate, at organization-wide committees (e.g., Medical Executive Committee, Clinical Quality Committee, Safety Committee, Hospital Infections Committee, Pharmacy and Therapeutics Committee) and at the department and institute quality improvement forums.

2) *Safety Rounds*

The safety of the environment of care and the safety of patient care processes are the focus of safety rounds conducted in all patient care areas in the Clinical Center. A team of Clinical Center senior staff responsible for patient safety (e.g., representatives from the Office of the Deputy Director for Clinical Care, the environment of care safety officer, pharmacy staff, the nursing quality officer, the occurrence reporting system manager) tour each area and query staff regarding patient safety and environment of care issues.

Information collected during safety rounds is summarized and forwarded to patient care unit and clinical department managers for use in local performance improvement activities. Safety rounds data are discussed, as appropriate, at organization-wide committees (e.g., Medical Executive Committee, Clinical Quality Committee, Safety Committee, Hospital Infections Committee).

3) *Leadership rounds*

Organizational leaders are encouraged to make rounds in their respective areas on a periodic basis. The rounds provide an opportunity for the leadership to talk directly with the staff about staff perceptions of barriers to providing safe patient care. Some departments have formalized this process to include all levels of the leadership team. For instance, nurse managers receive a list of questions, developed by the Nursing Department Quality Office, which includes critical issues to be reviewed with staff during rounds. The questions are intended to facilitate identification of real and/or potential system failures and/or knowledge deficits in the department. The responses are collated and presented to the division for discussion and action. Global issues are handled at the division level and unit-specific issues are handled by the leadership team and staff on the unit.

4) *Nosocomial Infections Surveillance*

Nurse Consultants and Infection Control Specialists are assigned to specific nursing units and perform daily microbiologic surveillance of Clinical Center patients to note case clustering and unusual pathogens and record all those causing infection. This process involves collection and review of data from various sources, and maintaining an extensive computerized database. The database is used to calculate infection rates, determine infection incidence and trends, and generate monthly and/or quarterly nursing unit infection reports. The Hospital Epidemiology Service (HES) staff visit targeted inpatient units a minimum of once a week to review charts and interact with staff on issues pertaining to infection surveillance and control. Targeted priority-directed surveillance is conducted for ventilator-associated pneumonia, and central-

venous access bloodstream infections. The HES staff conduct investigations of outbreaks or potential outbreaks of nosocomial infections as they occur among patients, visitors and staff. These may involve varicella exposures among pediatric and immunosuppressed patients and hospital staff, scabies outbreaks, patients with antibiotic-resistant organisms, parvovirus and tuberculosis exposures. The extent, complexity, and types of investigations can vary. Although some investigations can be completed relatively quickly, others may take months to investigate and may involve extensive chart review, epidemiologic studies (case-control studies), review of procedural techniques, specialized laboratory testing, and/or microbiologic culturing of patients, equipment, and the environment.

Surveillance data are reviewed in detail at the Hospital Infections committee and are disseminated to local patient care units, as appropriate.

5) *Risk Assessments*

Prospectively identifying potentially unsafe patient care and environmental situations is critical to a robust patient safety program. Formal risk assessments are conducted annually on all patient care units and in clinical departments. In addition, focused assessments are conducted to address specific areas of risk identified by organizational monitoring activities.

Data collected from the assessments are used to guide staff education and to identify areas where more intense assessment techniques may be required (e.g., use of Failure Mode and Effects Analysis or sentinel event management processes).

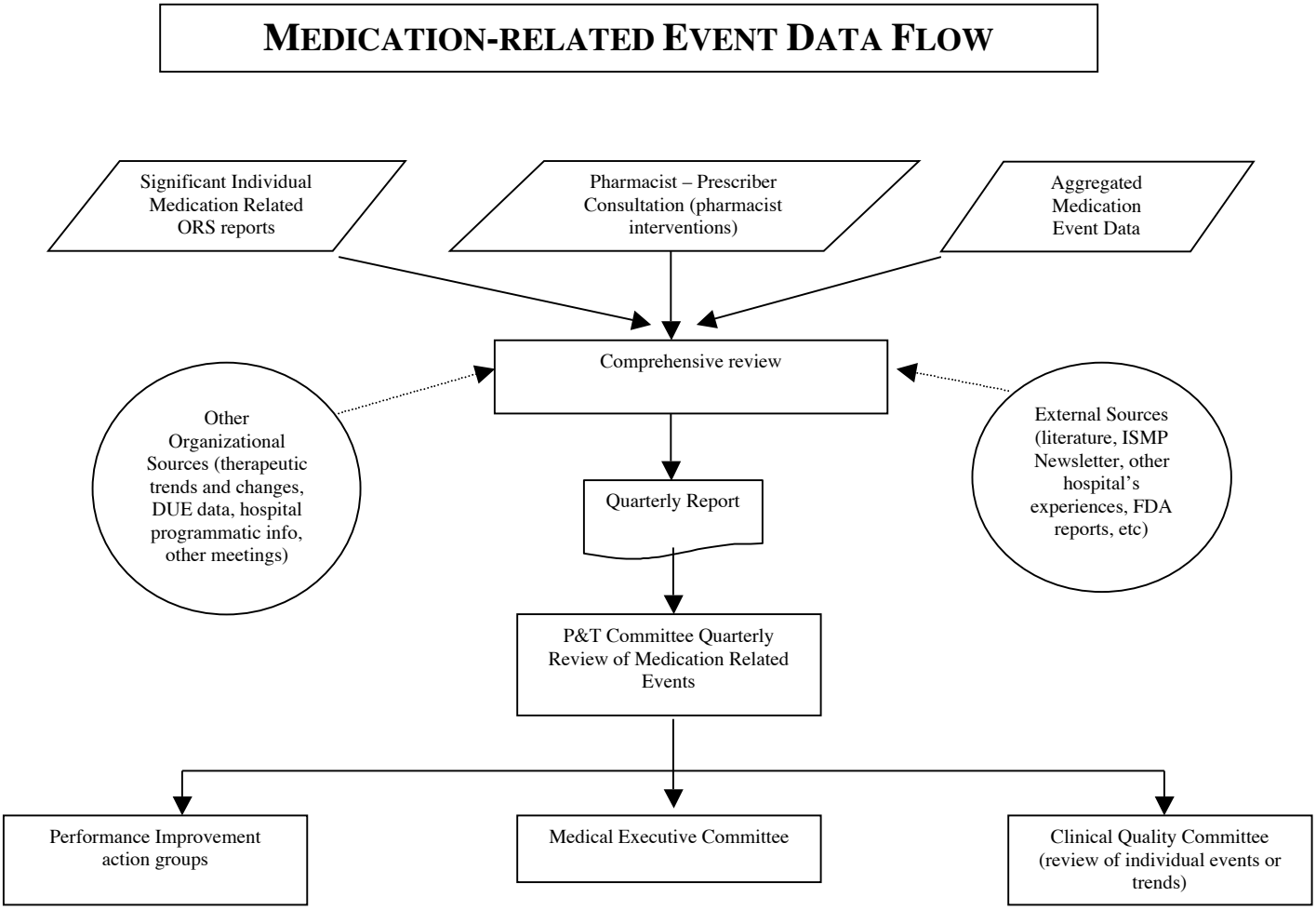
6) *Medication Errors/Pharmacy Interventions*

The CC Pharmacy department collects medication-related event data from several sources, both internal and external to the organization. The primary internal data sources are:

- Occurrence reporting system (ORS): any event suspected to be a medication error or that could lead to an error is reported via the Occurrence Reporting System (ORS), including errors that are caught before they get to the patient, the "near misses." The pharmacy quality officer and other hospital managers are notified via e-mail immediately when a report is entered for their area.
- Pharmacists' intervention data: consultations initiated by pharmacists with prescribers to adjust therapy or to correct prescribing errors. The prescriber receives immediate notification and feedback by a pharmacist about the event. Serious potential errors in chemotherapy prescribing are summarized and reported to National Cancer Institute Clinical Director and branch chiefs.

These data are aggregated and analyzed quarterly for notable trends or signal events that identify opportunities for improvement, particularly those involving high risk, high volume, or problem-prone processes. A summary with recommendations for further action is reported to the Pharmacy and Therapeutics Committee. ORS and intervention data are also supplied as needed to other action groups, such as performance improvement teams, the Medication Occurrence Review and Evaluation

Committee (MORE), which reviews pediatric medication events, the chemotherapy error prevention task force, the Patient Controlled Analgesia Task force, and others.



7) Staff Perceptions Regarding Patient Safety

Biennial Employee Perception Survey

In 2002, the Clinical Center, in collaboration with the National Research Corporation/Picker Institute, conducted a Clinical Center-wide survey of staff regarding their perceptions of the clinical and operational support provided by the Clinical Center. The results of this survey will serve as a baseline for future surveys aimed at assessing employee perceptions. An extensive assessment of staff perceptions about patient safety issues was included in the employee survey. The following questions were asked of staff relative to patient safety (responses were captured using a Likert-like scale):

- Is the Clinical Center genuinely concerned about patient safety?
- If you made an error that affected a patient would you feel comfortable reporting it?
- If you made a mistake that affected a patient, would you feel comfortable using the Occurrence Reporting System (ORS) to report it?
- If you found an error in someone else's work that affected a patient, would you feel comfortable reporting it?
- I am provided with adequate resources to accomplish my job safely.
- I am embarrassed when I make a mistake in front of other staff.
- If I make a mistake while I am working and nobody notices, I do not tell anyone.
- Clinical Center leadership punishes people who report errors or safety discrepancies.
- Staff in the Clinical Center are willing to report errors, close calls, safety violations, unsafe behavior, or hazardous conditions.
- When I report an incident (error, close call, etc.) in the ORS, the Clinical Center uses that information to improve patient and staff safety.
- I have learned to do my job better by learning about mistakes made by other staff member.
- Within the CC, good communication about safety issues flows up and down the chain of command.
- I believe errors occur frequently in the CC.
- When somebody else makes a mistake I would like to know about it so I don't make the same mistake.
- When I make a mistake, I do not want anyone else to know about it.

Improvement activities have been identified and initiated based on these survey data. Information about the employee survey is disseminated at the organizational level via the Medical Executive Committee and Board of Governors and at the local level through existing committee and programmatic meetings.

8) *Patient Perceptions Regarding Patient Safety*

In 1998, the Clinical Center partnered with the Picker Institute to measure patient perception about the care provided to them as participants in a clinical research protocol. A follow-up survey was conducted in 2002. Included in the 2002 survey were questions designed by the National Research Corporation and the Picker Institute to assess patients' perceptions of activities that did, or did not, occur during their Clinical Center stay that might potentially impact their safety. The following questions were asked of Clinical Center patients about patient safety (responses were captured using a Likert-like scale):

- Did you have to explain things that the staff should know multiple times?
- Did you receive the wrong medications or wrong dosage?
- Did family or friends have to say or do something about your care?
- Was the staff in too much of a hurry?
- Did the nurses respond to the call button quickly?

Improvement activities have been identified and initiated based on these survey data. Information about the patient survey is disseminated at the organizational level via the Medical Executive Committee and Board of Governors and at the local level through existing committee and programmatic meetings.

9) *Patient Representative*

The Clinical Center patient representative is a critical interface directly between patients and the hospital leadership. The patient representative hears from patients, first-hand, about real and potential patient safety issues. This information is communicated to the appropriate organizational staff. The patient representative's valuable patient-centric perspective makes he/she an important member of many Clinical Center committees and performance improvement teams.

10) *Patient Advisory Group*

The Patient Advisory Group provides advice to the Director of the Clinical Center regarding issues that directly impact patient and their families. This group provides an excellent sounding board for the Clinical Center leadership about patient care and service initiatives, including patient safety issues.

VI. SENTINEL EVENT MANAGEMENT AND THE USE OF ROOT CAUSE ANALYSIS FOR "NEAR MISSES"

The prevention, early detection, and effective management of untoward clinical events or significant "near misses" is critical to assuring quality patient care at the Clinical Center. To identify and manage these events effectively, the Clinical Center has developed a robust sentinel event management process. The process begins with continuous surveillance for clinical care occurrences that result in, or may have potentially resulted in, harm to the patient. Sources of this surveillance data are outlined in Section V, B.

The Medical Administrative Policy M00-2, "*Identification and Management of Sentinel Events",* provides guidance for managing an organizational response to a sentinel event. Organizational commitment to this process is demonstrated by the presence of the management of sentinel events on the Clinical Center's Strategic and Operating Plan.

The Clinical Center leadership appreciates the organizational learning that occurs as a result of patient safety "near misses". To assure that these events are rigorously studied, significant near misses are investigated using the Root Cause Analysis process. Results from these investigations are shared organization-wide in an effort to avoid similar, or more severe, adverse occurrences in the future.

VII. Strategies for Continually Assessing and Reducing Risk

A. Processes for Identifying High Risk Processes

All care is provided at the Clinical Center in the context of a narrowly defined clinical research protocol. Prior to implementation of a clinical research study, the protocol undergoes multiple levels of scientific, clinical and operational review. This layered review process allows the organization to proactively identify new process/procedures prior to implementation of the protocol. When a new process/procedure is identified, the investigator collaborates with the nursing staff and other disciplines, as appropriate, to discuss the new process/procedure/technology and to develop training programs to assure staff competence with the new process/procedure/technology. Ancillary departments are included in this collaborative process to assure that support infrastructure (supplies, pharmaceuticals, equipment, ancillary support training) are in place prior to implementation of the clinical research protocol. Examples of high-risk new procedures associated with protocol implementation include islet cell transplantation, management of severely schizophrenic children, administration of interleukins, etc.

To assure safe implementation of new procedures and therapies in high-risk environment of the operating room, the Surgical Administrative Committee has developed a policy that guides the introduction and use of novel therapies and procedures in the operating room.

B. Employee and Patient Risk Assessments

The Clinical Center's approach to prospectively identifying safety risks is described in Section V, B, 4.

C. Failure Mode and Effects Analysis

A proactive approach to risk reduction begins with an evaluation of critical processes of care. Prospective risk assessment recognizes that things can and do go wrong. The Clinical Center conducts Failure Mode and Effects Analysis (FMEA) to identify and reduce hazards in the clinical research environment. The FMEA is an analytical method used to determine the variety of ways processes can fail and the effect those failures might have on the performance of the process being studied. The Clinical Center has used the FMEA method to analysis key medication related processes and the transportation of patients on Special Respiratory Precautions Isolation to, and within, the Clinical Center.

VIII. PATIENT SAFETY RESEARCH ACTIVITIES

Medical errors remain a significant cause of morbidity and mortality among hospitalized patients in the United States. By the very nature of its mission, the Clinical Center, with its unique clinical research environment, is intrinsically associated with risk. To date from the literature, we have learned only a very limited amount about the epidemiology of medical errors that occur in healthcare institutions. Our patient safety research protocol is designed to provide insight into the epidemiology of medical errors in our unique institution. The study is divided into four parts, the first three of which are designed: first, to help characterize the true denominator or universe of adverse events and errors occurring in our hospital; and, second, to determine, as best we can, what fraction of those events are currently being captured in our revised and reinvigorated Web-based Occurrence Reporting System.

We currently use our Occurrence Reporting System (in which more than 6,000 events are voluntarily entered annually) as the backbone of our patient safety efforts. Data from the system can be used to characterize the epidemiology of medical errors in our clinical research hospital, to develop performance improvement projects to attempt to decrease errors, and to assess the efficacy of interventions arising from these performance improvement activities.

In the second phase of the study we propose to evaluate, in a pilot project, the use of biometric technology as an approach to assessing (and preventing) medical errors occurring in chemotherapy administration. Again, these data can be used as a fulcrum for improvement initiatives. We hope to develop a biometric/bar-coding system that will directly link patients, providers and medical orders (in the pilot project – orders for chemotherapy administration). Once this system has been developed and tested, we hope to generalize its use to other institutional systems (e.g., the Laboratory Medicine Department, the Transfusion Medicine Department, the Imaging Sciences Program).

These projects align directly with the Clinical Center's mission and vision and also connect directly to our ongoing patient safety program.

IX. CLINICAL CENTER CONTRIBUTIONS TO FEDERAL AND NATIONAL PATIENT SAFETY INITIATIVES

As an agency of the Department of Health and Human Services, the National Institutes of Health often is consulted by the Executive branch, Congress and other Federal agencies regarding issues of clinical research support and healthcare delivery. As the hospital at NIH, Clinical Center staff are called on to participate in initiatives addressing such issues as care delivery, patient safety, and performance measurement in acute care settings. Clinical Center staff have been active participants and consultants for the following organizations and projects:

- National Quality Forum
    - reviewed and participated in Forum discussions regarding the development of performance measures for patient safety

- QuIC – (The President's Quality Interagency Coordination Task Force – the QuIC's goal is to ensure that all Federal agencies involved in purchasing, providing, studying, or regulating health care services are working in a coordinated way toward the common goal of improving quality of care).
    - The CC participated in the performance improvement and patient safety subcommittees of the QuIC
    - As members of the Patient Safety Report Team of the QuIC, Clinical Center staff received the DHHS Secretary's Award for Distinguished Service.
- Agency for Healthcare Quality and Research
    - Consulted regarding the development of the national patient experience (perception survey) initiative piloted by the Centers for Medicare and Medicaid Services in 2003.